CONTRAST ECHOCARDIOGRAPHIC EXAMINATION OF LEFT HEART CHAMBERS AFTER INTRAVENOUS INJECTION OF A NEW SACCHARIDE BASED CONTRAST AGENT IN HUMANS

Reinhard Schlief, M.D., Ph.D., Thomas Staks, M.D., Marianne Mahler, M.D., Michael Rufer, Thomas Fritzsch, DVM, Ph.D., Wolfgang Seifert, M.D., Ph.D.. Departments of Clinical Research Diagnostic and Human Pharmacology, Schering AG Berlin/Bergkamen, FRG

The aim of this study was to assess the diagnostic efficacy, tolerance and effective dosage range of a new transpulmonary contrast agent (SH U 508/galactose-microparticles). SH U 503 was prepared five minutes before injection by transferring the appropriate amount of sterile water required to obtain the desired concentration into a vial containing specially manufactured microparticles and shaking it vigorously for about five seconds.

After giving informed consent, five healthy male volunteers with a mean age of 28 years (25 to 31) each underwent a total of 24 echocardiographic investigations before and after injection of different doses of SH U 508 and placebo (physiologic saline). Vital signs such as ECG, heart rate and blood pressure were continuously recorded throughout the procedure and a wide variety of parameters in blood chemistry, hematology and urinalysis were measured.

We found reproducible adequate contrast effects in the left heart cavities after injections of 300 and 400 mg/ml and volumes between 4 and 16 ml, homogeneously outlining the LV during the entire cardiac cycles for a period of up to several minutes. No imaging problems of the LV walls due to increased attenuation occurred.

The contrast injections were well tolerated in all concentrations used without any reported side effects or clinically relevant changes of vital signs, blood chemistry or hematology.

MULTICENTER REGISTRY OF CORONARY ATHERECTOMY USING THE TRANSLUMINAL EXTRACTION-ENDARTERECTOMY CATHETER.

Richard S. Stack, MD, FACC, Harry R. Phillips, MD, FACC, Peter J. Quigley, MD, James E. Tcheng, MD, Robert P. Bauman, MD, E. Magnus Ohman, MD, William W. O'Neill, MD, FACC, Joseph T. Galichia, MD, FACC, Craig Walker, MD, FACC. Duke University, Durham, NC.

The transluminal extraction-endarterectomy catheter (TEC; InterVentional Technologies Inc., San Diego, Ca.) consists of a flexible, hollow torque tube with a conical cutting head that rotates over a central guide wire at 750 rpm. Excised debris is continuously extracted by vacuum during periods of cutter activation. To date, 66 patients (mean age = 57 years; 82% males) have been entered into a 4-center registry for the treatment of symptomatic coronary artery disease (47% stable angina; 36% unstable angina; 17% myocardial infarction). The target lesions were located in the LAD (42%), RCA (42%), CIRC (9%), saphenous vein graft (5%), and a protected left main stem (2%). TEC alone was performed in 45 pts, and TEC with adjunctive PTCA in 21 pts. The procedural success rate (≤50% residual stenosis) was 92% (61/66 pts). There were no instances of distal embolization. The 5 pts who were not successfully treated all underwent successful immediate bypass surgery. There was one in-hospital death in a pt admitted with AMI and pulmonary edema who underwent successful TEC & PTCA (autopsy showed patent vessel and massive infarction). One pt reoccluded and one restenosed in-hospital and were treated successfully with PTCA and CABG respectively.

Conclusions: Initial results of this ongoing registry show a high procedural success rate for extraction of coronary plaque without evidence of distal embolization.

Wednesday, March 21, 1990
2:00PM-3:30PM, Room 43
Atherectomy

DIRECTIONAL CORONARY ATHERECTOMY: SUCCESS AND COMPLICATION RATES AND OUTCOME PREDICTORS.

John Simpson, M.D., F.A.C.C., Michael Rowe, M.B., B.S., Gregory Robertson, M.D., Matthew Selmon, M.D., James Vetter, M.D., Lissa Braden, B.S., Tomoaki Hinohara, M.D.. Sequoia Hospital, Redwood City, CA.

This series consisted of 260 consecutive patients (pts) with 308 lesions who underwent directional coronary atherectomy (DCA). Successful DCA (defined as <50% residual stenosis and >20% reduction of stenosis) was achieved in 91% of lesions. The average stenosis of 76 ± 14% was reduced to 13 ± 22%. Complications were as follows: no deaths, coronary surgery (CABG) in 9 pts (3.5%), Q wave infarct in 4 pts (1.5%) and perforation (no hemopericardium) in 3 pts (1.2%). Abrupt vessel closure following successful DCA occurred in only 2 patients. Of 17 clinical and angiographic factors analyzed, the significant predictors for success were as follows: previous angioplasty (93% success vs 86% if no previous angioplasty p<0.05), vessel involved (left main (n=15) 77% success, left anterior descending (n=146) 95%, circumflex (n=9) 75%, right coronary (n=74) 84% and saphenous vein grafts (n=64) 92% p<0.05) and absence of vessel calcification (96% success vs 66% for calcified lesions, p<0.0001). No factors were found to be predictors of need for CABG.

In conclusion, DCA is safe and effective with higher success rates particularly in lesions with prior PTCA, in left anterior descending arteries and in non-calcified vessels.

RESTENOSIS FOLLOWING DIRECTIONAL CORONARY ATHERECTOMY OF NATIVE CORONARY ARTERIES.

Tomoaki Hinohara, M.D., F.A.C.C., Michael Rowe, M.B., B.S., Mary Ellen Sipperly, R.N., M.S., Danna Johnson, M.D., Gregory Robertson, M.D., Matthew Selmon, M.D., James Leggett, M.D., John Simpson, M.D., F.A.C.C.. Sequoia Hospital, Redwood City, CA.

The aim of this study was to evaluate restenosis (RS) in native coronary arteries following successful directional coronary atherectomy (DCA) and identify associated factors. Of 91 eligible patients (pts), angiographic follow-up was obtained in 75 pts (82.4%) with 91 lesions at six months or earlier if symptoms recurred. Of the 16 pts without angiographic follow-up, 15 (94%) were asymptomatic. Cineangiograms were quantitatively analyzed using electronic calipers and RS was defined as >50% stenosis. RS was observed in 37 lesions (40.2%). Eleven clinical, angiographic and procedural factors were evaluated.

	Restenosis		p
Location: Proximal	26% vs 61%	Mid-distal	0.002
Vessel size: ≥3.25mm	23% vs 53%	<3.25mm	0.02
LD ratio: <3	31% vs 58%	≥3	0.04
Prior PTCA: ≤1	30% vs 50%	≥2	0.07

(LD ratio= Lesion length/vessel diameter)

Presence of media or adventitia, device size, vessel device ratio, vessel distribution, post procedure diameter or residual stenoses were not predictive of restenosis.

In conclusion, incidence of RS following DCA in native coronary arteries depends upon lesion location, lesion length and vessel size.